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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,345	03/24/2005	Ubaldo Conte	28069-603 NATL	3809

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EXAMINER

HAWES, PILI ASABI

ART UNIT. PAPER NUMBER

1615

DATE MAILED: 03/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/507,345

Applicant(s)

CONTE ET AL.

Examiner

Pili A. Hawes

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Summary***

Receipt of the Information Disclosure Statement(s) filed 02-07-2005 is acknowledged. Claims 1-17 are pending in this action. Claims 1-17 are rejected.

### ***Double Patenting***

Applicants' filing of the terminal disclaimer to overcome the double patenting rejection made in the previous office action is acknowledged, and therefore the double patenting rejection is withdrawn.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Edgren et al. US 4503030.

Edgren discloses an oral osmotic device composed of a semipermeable material surrounding a compartment containing an active agent (col. 10, lines 55-68, and col. 11, lines 1-5). Example 1 discloses the composition comprises 2.9%

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hydroxypropylmethylcellulose (col. 9, line 43) and 25% cellulose acetate (col. 9, line 51).

The composition also comprises effervescent and disintegrating agents, diluents, and wetting agents (col. 9, lines 1-5). The composition further comprises other hydrophobic diluents, binders, glidants, lubricants, etc. (col. 7, lines 35-45). The composition also contains insoluble coating film made of polyacidic polymers (col. 6, lines 60-68). The dosage form also contains an expression passageway that includes an aperture, orifice, bore, hole, or the like through the wall (col. 8, lines 25-30). Example 1 further discloses the process of drilling the passageway using a laser (col. 9, lines 61-62).

Claims 1, 16, 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Theeuwes et al. US 4088864.

Theeuwes discloses a method of drilling a passageway into tablets (abstract). Figure 1 discloses a tablet dosage form comprised of an active agent containing core that is surrounded by a semipermeable membrane (col. 40-65). The laser for the invention operated at a power range from 15-30 watts in the case of a CO<sub>2</sub> laser (col. 4, lines 35-40).

Claims 1-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Faour US 6599284 B2.

Faour discloses a controlled release osmotic device comprised of an outer layer or external coating (optionally) containing active ingredient (2), an intermediate layer forming a semipermeable membrane (3), and an inner layer or core containing active ingredient (4) (Figure 4). The dosage form also comprises a passageway (5) formed by laser incision (col. 13, lines 48-55), (Figure 4). The reference also teaches the addition

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of osmopolymers (col. 16, lines 1-45), and disintegrating agents (col. 18, lines 25-38).

The reference further discloses that the outer layer or external coating layer may contain the same or different active ingredients as the inner layer (col. 13, lines 5-7).

Example 1 discloses the composition of the inner core, which comprises more than 49% by wt polymeric material (col. 24, lines 15-25). Example 1 also discloses the use 5% by wt of polyethylene glycol (col. 24, lines 25-30). Faour incorporated by reference

Theeuwes et al. US 4088864, which discloses the laser source as CO<sub>2</sub> and the output of 20W. Therefore the process claims are also anticipated by this reference.

### ***Response to Arguments***

Applicant's arguments filed 12-22-2005 have been fully considered but they are not persuasive. Applicants argue that the composition of Edgren fails to anticipate their composition because the Edgren describes a dosage with a semipermeable polymer coating while Applicant's dosage form is coated with an insoluble coating. Claim 1 of the instant application does not recite specific insoluble polymers, which are used to coat the instant dosage form. However, page 8 of Applicant's specification recites the polymers that are used as insoluble polymers, these are "acrylates, methacrylates, and ethylcelluloses". These polymers are also blended with other polymers such as polyoxyethyleneglycols (page 8, line 31), to form the "insoluble coating" of the instant invention. Applicant's specification goes on to describe a second coating comprising "acrylic and methacrylic copolymers, cellulose aceto-propionate" among others. Thus the instant invention is intended to be a blend or mixture of various polymeric substances which exhibit different solubilities based on the pH of the environment the

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dosage form is subjected to. Edgren also teaches a blend of the same polymers.

Edgren defines these polymers differently than Applicant, in that the reference defines cellulose acetate propionate as "semipermeable polymers" (col. 5, lines 43-54). Edgren further describes polymers such as polymethacrylic acid esters as "materials that keep their physical and chemical integrity in the stomach" (col. 6, lines 20-25, 65-67). Thus the same polymers that Applicants describe as "insoluble or impermeable to aqueous fluids" are taught and used by Edgren in coating the dosage form of the prior art.

Applicants further teach combining enterosoluble polymers such as those taught by Edgren to further coat the dosage form. This teaching does not differentiate from the prior art in that the same polymers such as acrylic and methacrylic copolymers, cellulose aceto-propionate and hydroxypropylmethylcellulose are also taught by Edgren and used in combination with polymers that are "insoluble and impermeable to aqueous fluids".

Applicants further argue that Edgren does not teach forming incisions in the polymeric film, however Edgren clearly teaches forming apertures in the film, which is interpreted to be the same as an incision.

Although Applicant's intent in defining the polymer as "insoluble and impermeable to aqueous fluids" was to differentiate their invention from prior art that describes semi-permeable coatings, the invention as claimed fails to differentiate. The fact is that the same polymers are used in Edgren that are described, but not claimed in the instant application, and thus the invention is anticipated by Edgren.

Likewise, Applicants arguments do not overcome the rejection made over Theeuwes et al. As has been demonstrated in the reference of Edgren, the term "semipermeable" can be used to describe the same polymers that Applicant term "insoluble and impermeable to aqueous fluids". As the instant claims do not recite any particular polymers that are used in the instant coatings, the reference of Theeuwes is still deemed to anticipate the instant invention.

In response to Applicants arguments regarding the Faour reference. Applicants' attention is drawn to col. 10, lines 25-30 of Faour, which teaches polymers of methacrylates, and also to column 12, lines 27-45, which teaches combining these polymers with plasticizing agents. Thus clearly the polymer coating described by Faour as "semipermeable" is also the same as the polymer coating described by applicants on page 8 of the specification because the same ingredients are used. As discussed in the previous office action and repeated above, Faour teaches preformed passageways, such as pores, holes or apertures. Apertures are interpreted to be the same as incisions, and thus the dosage form disclosed by Faour still anticipates the instant claims.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

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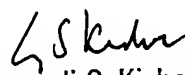
TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pili A. Hawes whose telephone number is 571-272-8512. The examiner can normally be reached on 8-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

P.A. Hawes  
Examiner-1615

  
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